MAR 18 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K040073.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675; FAX: (847) 996-4655 Contact person: Nina Gamperling Date prepared: January 13, 2004
2. Name of Device:	Trade or proprietary name: Sysmex® Automated Hematology Analyzer, XE-2100 Series Common name: Automated Hematology Analyzer. Classification name: Sysmex® XE-Series, Automated Hematology, an Automated Differential Cell Counter (21 CFR 864.5220) is a Class II medical device.
3. Predicate Method:	The Sysmex® XE-2100 Series Body Fluid Application claims substantial equivalence to the pre-amendment predicate method for the enumeration of WBCs and RBCs of manual cell counting in a counting chamber by a skilled, competent technologist.
4. Device Description:	The XE-2100 Series is an automated hematology analyzer previously cleared by the FDA. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells gives an image of each cell detected in the specimen.
5. Intended Use:	The Sysmex® XE-2100 Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The Body Fluid Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, scrous fluid and synovial fluid to the XE-2100 Series, providing enumeration of the WBCs and the RBCs.
6. Substantial equivalence-similarities and differences	The following table compares the XE-2100 Series Body Fluid Application with the predicate method.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

Comparison to Predicate Method

	Predicate Method	**XE-2100 Series Body Fluid Application**
	Manual Method	**Automated Method**
Intended Use	To provide a quantitative determination of blood cells in cerebrospinal fluid, serous fluid and synovial fluid.	Same as predicate method
Methodology	Cell count is performed manually in a counting chamber by a skilled competent technologist.	Cell count is performed on an automated hematology analyzer.
Specimen Type	Cerebrospinal fluid, Serous fluid, Synovial fluid	Same as predicate method
Performance	Method of cell counting using a microscope established as the predicate method.	Comparison to manual count showed good correlation.
Pro/Con	The reproducibility and accuracy of the manual method will vary due to the differences in technologist skill and experience. It is a labor intensive and time-consuming method.	The reproducibility and accuracy of an automated method is more consistent since this method is not subject to the variation of the manual method. A large number of cells can be analyzed and several parameters (i.e. forward scatter [FSC], side scatter [SSC], and fluorescent labels) rather than morphological appearance alone can be used to identify the blood cells.

7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the automated method to the predicate method. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 18 2004

Ms. Nina M. Gamperling
Manager, Regulatory Affairs
Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, IL 60060

Re: k040073
Trade/Device Name: Sysmex® XE-2100 Series, Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: January 13, 2004
Received: January 16, 2004

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040073

Device Name: Sysmex® XE-2100 Series, Automated Hematology Analyzer

Indications For Use:

The Sysmex® XE-2100 Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The Body Fluid Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid and synovial fluid to the XE-2100 Series, providing enumeration of the WBCs and the RBCs.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(k) K040073